Complete Summary

GUIDELINE TITLE

Aspirin therapy in diabetes.

BIBLIOGRAPHIC SOURCE(S)

Colwell JA. Aspirin therapy in diabetes. Diabetes Care 2003 Jan;26(Suppl 1):S87-8. [4 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Cardiovascular disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for aspirin therapy in patients with diabetes mellitus

TARGET POPULATION

Adults with type 1 or type 2 diabetes mellitus who have established cardiovascular disease or risk for cardiovascular events

INTERVENTIONS AND PRACTICES CONSIDERED

Aspirin therapy

MAJOR OUTCOMES CONSIDERED

Risk of primary or secondary vascular events (i.e., myocardial infarction or recurrent myocardial infarction)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The paper was peer-reviewed, modified, and approved by the American Diabetes Association's Professional Practice Committee in May 1997 and by the Executive Committee in June 1997. The paper was most recently reviewed and revised in 2000.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Please note: This guideline has been updated as of January 2004. The National Guideline Clearinghouse is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

1. Use aspirin therapy as a secondary prevention strategy in diabetic men and women who have evidence of large vessel disease. This includes diabetic men and women with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina.

2. In addition to treating the primary cardiovascular risk factor(s) identified, consider aspirin therapy as a primary prevention strategy in high-risk men and women with type 1 or type 2 diabetes. This includes diabetic subjects with the following:
    - A family history of coronary heart disease
    - Cigarette smoking
    - Hypertension
    - Obesity (>120% desirable weight); body mass index >27.3 kg/m^2 in women, >27.8 kg/m^2 in men
    - Albuminuria (micro or macro)
    - Lipids:
        - Cholesterol >200 mg/dl
        - Low-density lipoprotein (LDL) cholesterol $\geq$100 mg/dl
        - High-density lipoprotein (HDL) cholesterol <45 mg/dl in men and <55 mg/dl in women
        - Triglycerides >200 mg/dl
    - Age >30 years

    Use of aspirin has not been studied in diabetic individuals under the age of 30 years.

3. Use enteric-coated aspirin in doses of 81 to 325 mg/day.
4. People with aspirin allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy.
5. Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Secondary prevention trials: A meta-analysis of 145 prospective controlled trials of antiplatelet therapy in men and women after myocardial infarction, stroke or transient ischemic attack or positive cardiovascular history; a randomized controlled trial (the Early Treatment Diabetic Retinopathy Study); a randomized controlled trial of hypertensive patients (the Hypertension Optimal Treatment Trial).

Primary prevention trials: A randomized, placebo-controlled trial of male physicians (the U.S. Physician's Health Study).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Secondary prevention of cardiovascular events: A meta-analysis of 145 prospective controlled trials of antiplatelet therapy in men and women after myocardial infarction, stroke or transient ischemic attack, or positive cardiovascular history (vascular surgery, angioplasty, angina, etc.) estimated that 38 +/- 12 vascular events per 1,000 diabetic patients would be prevented if they were treated with aspirin as a secondary prevention strategy.

  These results are supported by the Early Treatment Diabetic Retinopathy Study (ETDRS). This population consisted of type 1 and type 2 diabetic men and women, about 48% of whom had a history of cardiovascular disease. The study, therefore, may be viewed as a mixed primary and secondary prevention trial. The relative risk for myocardial infarction in the first five years in those randomized to aspirin therapy was lowered significantly to 0.72 (confidence interval [CI] 0.55-0.95).

  In the Hypertension Optimal Treatment (HOT) Trial, aspirin significantly reduced cardiovascular events by 15% and myocardial infarction by 36%.

- Primary prevention of cardiovascular events: Subgroup analysis of diabetic physicians in the U.S. Physicians' Health Study revealed a reduction in myocardial infarction from 10.1% (placebo) to 4.0% (aspirin), yielding a relative risk of 0.39 for the diabetic men on aspirin therapy.

Subgroups Most Likely to Benefit:

In the meta-analysis of secondary prevention trials, proportional benefits of aspirin therapy were seen in all subgroups studied (males and females, patients with or without diastolic hypertension, those over or under age 65 years, diabetic and nondiabetic subjects). Absolute benefit was greater among those at high risk (over age 65 years, diastolic hypertension, diabetes).

POTENTIAL HARMS

- Bleeding episodes: A major risk of aspirin therapy is gastric mucosal injury and gastrointestinal hemorrhage. These effects are dose related and are reduced to placebo levels when enteric-coated preparations of 75 to 325 mg are used once daily. Minor bleeding episodes (epistaxis, bruising, etc.) may occur at low doses, probably from the effect of aspirin to inhibit the platelet release reaction. In several prospective studies, a trend for an increase in hemorrhagic stroke has been seen, but has not reached statistical significance. The Hypertension Optimal Treatment (HOT) Trial demonstrated that while fatal bleeding episodes, including intracerebral bleeding, were equal in the aspirin and placebo groups, nonfatal minor bleeding episodes were more common in the aspirin group.
- Effects on angiotensin-converting enzyme inhibitors: Aspirin therapy has been shown in secondary analysis to lessen the beneficial effects of angiotensin-converting enzyme (ACE) inhibitors in patients with established cardiovascular disease (e.g., prior myocardial infarction, angina, congestive heart failure). Therefore, alternative antiplatelet agents should be considered in these patients until more definitive results are available.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to aspirin therapy include allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding, clinically active hepatic disease, and age under 21 years. Additionally, aspirin therapy is contraindicated in patients who have established cardiovascular disease and are taking angiotensin-converting enzyme inhibitors.

QUALIFYING STATEMENTS

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The use of aspirin has not been studied in diabetic individuals under the age of 30.

Evidence is only one component of decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies such as the one adapted by the American Diabetes Association may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Colwell JA. Aspirin therapy in diabetes. Diabetes Care 2003 Jan;26(Suppl 1):S87-8. [4 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2000; republished 2003 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association received an educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2003 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author of Position Statement, Initial Draft: John A. Colwell, MD, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Please note: This guideline has been updated as of January 2004. The National Guideline Clearinghouse is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The recommendations in this paper are based on the evidence reviewed in the following publication:

- Aspirin therapy in diabetes (Technical Review). Diabetes Care 1997 Nov;20(11):1767-71.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. The NGC summary was updated on March 14, 2002 and April 21, 2003.

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